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Poland

Biotechnology

Poland publishes new draft law on cultivation 2008

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Report Highlights:

The Environment Ministry has published a draft law on cultivation of agricultural biotechnology crops that is restrictive. EU regulatory authorities have told Poland it must update its GM law, but the Ministry proposal creates new headaches designed to prevent planting. Regions may declare themselves GM-free and farmers violating the law can be sent to jail. The law heavily regulates scientific research and plant geneticists report that the conditions will prevent research. Poland has a severe outbreak of European Corn Borer that causes a \$400 million crop loss to corn farmers each year. GM varieties approved for planting in the EU and used in Spain and Czech Republic would recover that loss. Poland has the highest animal feed prices in Europe and imports more pork than it exports. Polish animals are fed GM corn from other countries. Imported pork is raised on GM feeds. Polish farmers don't have a level playing field against other EU farmers and are losing out.

Includes PSD Changes: No Includes Trade Matrix: No Annual Report Warsaw [PL1] Poland's Ministry of Environment has published for public comment a law on the cultivation of agricultural biotechnology crops that is restrictive and raises the administrative risk for farmers for planting. The law attempts to comply with EU regulatory authorities that have told Poland it must update its GM law, but the Ministry proposal creates new headaches designed to prevent planting, not solutions. One of the misunderstandings caused by the approach of the new regulations is the issue of administrative risk. In the name of trying to control what farmers will do with new technology crop varieties, regulatory authorities place ex post facto requirements and audits that create many specific procedures and documentation that a farmer will have to do to avoid breaking a regulation. With strict fines in place, this type of "gotcha" attitude by regulators makes trying new technology too high a risk. A producer's cultivation plan will be checked by the local environmental control agency and they will have to document neighbors' support for their biotechnology crop. Producers will be audited to discover, among other procedures, did the producer comply with notification procedures. Did the producer give a notice to local farmers 3 months before starting production and he has record that they agreed with it? Do they have free, buffer zones located with the crop? The auditor has the right to review those measurements. The law strictly enforces traceability. The Inspectorate can check documentation to confirm where exactly the products go, who buys it, and in what amounts. If they sell, warehouse, or transport items they have to notification the buyer that the crop is a modified plant. Most producers think they cannot comply with such strict regulations without assistance.

The law also updates the provisions for conducting experimental research with plants and transgenic modification. The Law is again strict and plant geneticists contacted by FAS Warsaw report that they could not research under many of the provisions. Some have commented publicly that the new law is prohibitive to research.

The major provisions of the draft indicate:

- Polish farmers' plantings would be dependent on approval of local authorities who would be allowed to create "GMO free zones". In such zones planting e.g. GMO corn would be prohibited (with penalty of PLN 20,000 (\$9,000); plus PLN 3,000 (\$1400) per hectare.
- If a farmer would trade GMO product not approved by authorities (incl. seeds), he could be penalized by imprisonment of up to 3 years.
- Farmers would need to separate GMO plantings by special safety zones (size to be determined and published by Min of Environment in implementing regulations), with a possibility of neighbor farmers protesting the GMO plantings to be placed in their neighborhood. The Government would resolve disputes.
- GMO's for scientific research (genetic engineering) and seed marketing will be strictly regulated. Planters should arrange a proposal with all information and documents needed at every stage. They wait for allowances from the Ministry of Environment and they have to bring all the paperwork the Ministry needs for their application to be considered. Any scientific research unit wanting to conduct research planting will be obligated to make the results of their research available to the public.
- Farmers would pay a deposit to cover any potential legal suits in cases of dealing with a list of products classified as, "the most dangerous organisms" before planting.
- There is an obligation to label the product as genetically modified. Products which are meant to be processed and have modified organisms in amount not over 0.9% should not be marked.

- There are some border controls described in the draft law that imagine rechecking the properly cleared documents of GMOs arriving in Poland from other EU member states. GMOs from non EU member states would pass the border control executed by proper organ of inspection. If product arrives to Poland through another member country and it did not pass the border control with proper inspection, it should be controlled once again by units in Poland and there should be proper report made.
- Research institutes and farms should inform employees about the content of safety regulations; workers must sign a statement that they have been informed that they are working with GMOs.

The specific steps required for using GMOs'

Seed company sales requirements for the intentional release permission for introducing GMO's into the environment. Permission is requested from the Ministry of Environment:

- 1. Full name and address of the user, name and address of the company
- 2. Description of activities, main goals, description of modified organisms
- 4. Full names of people who are responsible for safety activities and their work qualifications
- 5. Information about conditions of intentional release (place, environment, main goals, interactions with all the organisms)
- 5. Description of control possibilities
- 6. Estimation of possible danger prepared for every kind of organism being used in the place
- 7. Description of the safety measures
- 8. Information about the proceedings with all kind of waste made at the place
- 9. Safety plan in case of breakdown or problem with the plant.

The permission or denial is released in 30 days.

Requirements for seed companies offering seeds into trade should include:

- 1. Full name and address of the user, name and address of the company
- 2. Description of activities, main goals, description of modified organisms in products
- 3. Estimation of possible danger prepared for every kind of organism being used
- 4. Description of the safety measures
- 5. Information about conditions of taking into the market (place, environment, main goals, interactions with all the organisms)
- 6. Description of control possibilities
- 7. Information of marking the product and decisions in trading with other countries
- 8. The source of organisms in products based on proper documentation

The permission or denial is released in 30 days.

Requirements for producers to request planting permission:

- 1. Full name and address of the user, name and address of the company
- 2. Description of modified organisms in products
- 3. Documentation of the location's record number
- 4. Description of the institution which gave out the seeds
- 5. Evidence of local farmer's deposit for damage allowance
- 6. Estimation of possible danger prepared for every kind of organism being used
- 7. Description of the safety measures

To raise a GM crop, users notify the Ministry of Environment, but they do not need a permit. Farmers should inform local farmers three months before planting that they will grow modified organisms. They should give a notice one month before sowing to the region Plant Protection and Environmental Control Agency (Wojewodzki Inspektorat Ochrony Roslin I

Nasiennictwa – the local institution that is connected to the National Plant Protection and Environmental Control Inspection of the Ministry of Environment – (Panstwowa Inspekcja Ochrony Roslin I Nasiennictwa - the national institution and deals with supervision of plant health. The local agency controls if farmers are monitoring the crops in the legal manner, so that they do not mix the seeds with those which are not modified or if they store plants so they cannot interfere with other crops. Users should inform people who would use warehouses or kinds of transport that they might have a contact with genetically modified organisms. Users should provide a book to help describe how to prevent mixing the plants, also they should provide documents of every trade of this product. The law requires many details from farmers. Farmers contacted by FAS Warsaw report they do not understand all these requirements and they do not think that it is possible to fulfill all the requirements. Its quite a lot to do.

Requirements for permission to perform genetic engineering. To be sent to the Ministry of Environment.

- 1. Full name and address of the user, name and address of the company
- 2. Full name of a person who is responsible for the institution's safety and his\her work qualifications
- 3. Description of institution including production facilities
- 4. Future activities
- 5. Category of danger defined in the work environment with the organism
- 6. Kinds of safety measures that could be used in case of emergency
- 7. Information about the processing of waste made at the location
- 8. Decision of veterinarian from the district that institution can keep animals for laboratory research when engineering involves animals

The permission or denial must be made in 45 days.

The representatives of auditing units are authorized to enter the premises two times or more during the calendar year. They can request documents, research data, or ask for oral or verbal explanations.

Proposal for the experimental testing of microorganisms (2nd danger category) permission to the Ministry of Environment:

- 1. Full name and address of the user, name and address of the company
- 2. Description of activities, main goals, description of modified organisms
- 3. Information about the proceedings with all kind of waste made at the place
- 4. Full names of people who is responsible for institution's activities safety and their work qualifications
- 5. Description of production facilities
- 6. Estimate of possible danger prepared for every kind of microorganism being used in the place
- 7. Description of the safety measures
- 8. Copy of the internal safety regulations for the employees
- 9. Copy of declarations which say that employees know and understand the safety regulations
- 10. Information about effective disinfection measures and danger of unauthorized release

The permission or denial must be made in 45 days.

Proposal for the experimental testing of microorganisms (3rd and 4th category of danger) permission to the Ministry of Environment:

1. Full name and address of the user, name and address of the company

- 2. Description of activities, main goals, description of modified organisms
- 3. Information about the processing of waste made at the location
- 4. Full names of people who are responsible for institution's activities safety and their work qualifications
- 5. Description of production facilities
- 6. Estimation of possible danger prepared for every kind of microorganism being used in the place
- 7. Description of the safety measures
- 8. Copy of the internal safety regulations for the employees
- 9. Copy of declarations which say that employees know and understand the safety regulations
- 10. Information about effective disinfection measures and danger of self spreading
- 11. Kinds of safety measures described
- 12. Safety plan in case of breakdown

The permission or denial is released in 90 days.

Experimental biotechnology is under many other conditions including:

- 1. A management plan must be in place on how to have the lowest possible danger of negative genetic cause
- 2. To use all practical technical security measures at the source of danger
- 3. To be aware of the duty which tells that people who deal directly with those organisms should use proper equipment and individual protection
- 4. To do regular checks of production facilities and safety devices
- 5. To monitor for signs of the organisms (3rd and 4th category) being accidently released from experimental usage.
- 6. To get special hygiene and safety training for the people who deal directly with those organisms at least 2 times per year
- 7. To create internal security commissions to monitor biological matters (3rd and 4th category)
- 9. To do written documentation of the duties
- 10. To place signs of biological danger in proper places
- 11. To prohibit eating, smoking, using cosmetics and food storage
- 12. To prohibit using oral pipettes in the facility
- 13. To have effective measures to disinfect the facility.

Other reports filed by FAS Warsaw on biotechnology...

PL 8003: Poland considers new legislation

http://www.fas.usda.gov/gainfiles/200802/146293707.pdf

PL 8020: Poland biotech feed ban impact

http://www.fas.usda.gov/gainfiles/200806/146294929.pdf